AF

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/077,194	12/04/1998	MANFRED BOHN	02481.1596	5713

22852 7590 01/17/2006

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP
901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER	
EPPERSON, JON D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 01/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/077,194	BOHN ET AL.	
	Examiner	Art Unit	
	Jon D. Epperson	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *38-42,48 and 53-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *38-42,48 and 53-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/30/05 (redone)*.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *11/30/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination (RCE)

1. A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection (e.g., see 2/22/05 Response). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/15/05 has been entered. Claims 38-42, 48 and 53-66 were pending. Applicants amended claims 38-42, 48, 53, 55-59 and 61-66. In addition, Applicants added claim 67. Therefore, claims 38-42, 48 and 53-67 are currently pending. An action on the merit follows.

Those sections of Title 35, US code, not included in the instant action can be found in previous office actions.

2. The restriction requirement dated 3/2/05 is hereby withdrawn in view of Applicants' arguments with regard to the reconstruction (e.g., see Interview Summary).

Withdrawn Objections/Rejections

3. All previous rejections are withdrawn in view of Applicants' arguments and/or amendments.

New Rejections

Claims Rejections - 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 38, 40, 41, 42, 48 and 65 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed had possession of the claimed invention. This is a new matter rejection.

A. Claims 38 was amended in 2/22/05 response to recite "... administering to the patient an amount effective for the treatment of seborrheic dermatitis of a composition comprising: (A) a sole active component consisting of at least one 1-hydroxyl-2-pyridone of formula I ... in free form or as a pharmaceutically acceptable salt ... wherein the composition has a pH ranging from about 4.5 to about 6.4" in lines 3-5 and the last line of the claim. However, the Examiner cannot find support for this claim limitation with regard to the "pharmaceutically acceptable salt" embodiment. For example, Applicants' specification states, "... when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids" (e.g., see specification, page 8, lines 30-32; see also Example 7 wherein "lactic acid" is used to adjust the pH). Furthermore, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "... acids per se possess an antimicrobial action, such as fumaric acid and azelaic acid. In this way the effect of the antimycotic in phase I as well as phase II is enhanced!"; see also paragraph bridging pages 9-10, "Examples of these acids are ... lactic"). Applicants have not shown where support for

this new genus of compounds that contains "1-hydroxyl-2-pyridone of formula I salt + "non-active" organic acids" can be found. If applicant believes this rejection is in error, applicant must disclose where in the specification support for this amendment can be found in accordance with MPEP 714.02. Therefore, claim 38 and all dependent claims represent new matter.

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 38-42, 48 and 53-67 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. For **claim 38**, the phrase "a sole active component consisting of at least one" is vague and indefinite. For example, it is not clear how "a sole active component" could be anything other than "exactly" one? That is, the term "a sole active component" is not consistent with the term "at least one" as used in the claim. In addition, the "pharmaceutically acceptable salt" embodiment requires two active ingredients, (1) the salt of a compound of formula I and (2) the organic acid that is used to adjust the pH (e.g., see specification, page 8, lines 30-32, "... when using the compounds in salt form, the adjustment of the pH range mentioned has to be carried out using organic acids"; see also Example 7 wherein "lactic acid" is used to adjust the pH; see especially dependent claim 65 wherein "lactic acid" is specifically required by the claims, which further limits

independent claim 38) and, as a result, the claim cannot be limited to a "sole" active ingredient. For example, organic acids, including lactic acid, are known to possess anti microbial action (e.g., see Lange, page 7, last paragraph, "... acids per se possess an antimicrobial action"; see also paragraph bridging pages 9-10, "Examples of these acids are ... lactic"; see especially, page 15, second set of ingredients, "lactic acid ... (bacterio and mycostatic agent)"). Thus, it is not clear how the composition comprises a "sole" active ingredients when more than one active ingredients are being claimed (e.g., formula I salt + lactic acid). Consequently, the metes and bound of the claimed invention cannot be determined. Therefore, claim 38 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

B. For **claims 38-42, 48, 53, 55-59, 61-67**, the term "seborrheic dermatitis" is vague and indefinite in view of the prosecution history. For example, Applicants state, "Dascalu et al. misuses dermatology nomenclature by confusing 'dandruff' with 'seborrheic dermatitis' ... Although seborrheic dermatitis involving the scalp may give rise to a mistaken diagnosis of dandruff, it is well understood in the field of dermatology that seborrheic dermatitis is a condition distinct from dandruff" (e.g., see 4/24/02 response, pages 19-20). Applicants define "seborrheic dermatitis" as "a disorder of the scalp which differs from simple dandruff by the presence of erythema as a sign of inflammation, by the greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes to other body sites" (e.g., see specification, page 1). Applicants further state, "Pityrosporum ... is assumed o be the cause of seborrheic dermatitis" (e.g., see specification, page 1, last paragraph). However, Dascalu

et al. disclose a treatment for the exact same symptoms as those defined in Applicants' specification (e.g., see Dascalu et al., line 12 wherein inflammation is disclosed; see also page 5, Table 1, patient 5, wherein a high degree of scaling is disclosed; see also page 5, Table 1, patient 2 wherein a high degree of "itching" is disclosed; see also Table 5, patient 5 wherein the overall severity of the dandruff is characterized as "severe" or, in Applicants' words, not just "simple dandruff"). In addition, Dascalu et al. explicitly state that their treatment inhibits the exact yeast, Pityrosporum (e.g., see Dascalu et al., line 13; see also claim 8). Thus, it is not clear what symptoms, underlying causative agents and/or other physiochemical factors Applicants are relying on to make this distinction (i.e., there is no basis for this assertion). Thus, the metes and bound of the claimed invention cannot be determined. Therefore, claims 38-42, 48, 53, 55-59, 61-67 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 39, 61-64 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Lagarde (WO 96/02226) (Date of patent is **February 1, 1996**) (translation provided) as evidenced by Wikipedia (e.g., Wikipedia, "Category: Surfactants" last modified 24 November 2005, page 1, accessed on 12/3/05 at http://en.wikipedia.org/wiki/Category:Surfactants).

For ***claims 39, 62 and 63***, Lagarde et al. (see entire document) disclose a novel combination product comprising an anti-fungal agent selected from the 1-hydroxyl-2-pyridones such as circlpirox or octopirox and, secondly, crotamiton as an antifungal agent activity enhancer (e.g., see Lagarde et al., abstract), which anticipates the claimed invention. For example, Lagarde et al. discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said combination (e.g., see page 5, middle paragraph, "Moreover, seborrheic dermatitis is more common in patients that have atopical background, cervico-cephalic atopical dermatitis, with the presence of orbicular anti-pitysrosporum specific Ig E in which the rate is highly correlated with the severity of the disease. With respect to dermatophytoses we can mention athlete's foot, scalp disease as well as all cases of onychomycosis. Given all of these pathologies, few therapies are actually effective"; see also page 6, paragraphs 3 and 4, "Therefore there is a real need for an anti-fungal product that would have different qualities ... the present invention deals with a new combination product, in which the synergistic combination offers improved anti-fungal activity"). In addition, Lagarde et al. discloses at least one 1-hydroxyl-2-pyridone of formula I as the sole active component (e.g., page 7 of the translation formula (I); see especially see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed). Furthermore, Lagarde et al. discloses, for example, the use of a surfactant (e.g., see page 16 of the translation, last paragraph, "It is quite evident that these formulas are not limiting and that it is important to make certain of the compatibility of surface-active agents with the combination 1-hydroxy-2-pyridone

/crotamiton according to the invention; see also Examples wherein surfactants like Cocamide DEA, Cocamide MEA, Cocamidopropyl betaine are disclosed). Lagarde et al. do not state that Cocamide DEA (non-ionic), Cocamide MEA (non-ionic), Cocamidopropyl betaine (amphoteric) are "surfactants", but the Examiner contends that these would be inherent properties of these molecules as exemplified by Wikipedia (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claim 61***, Lagarde et al. disclose the cyclohexyl R4 group (e.g., see page 9, first full paragraph, wherein ciclopirox (R1=cyclohexyl, R2=R4=H and R3=CH3) or octopirox (R1=2,4,4-trimethylpentyl, R2=R4=H and R3=CH3) are disclosed).

For ***claim 64***, Lagarde et al. discloses at least one "additional" surfactant such as cocamidopropyl betaine + Cocamide MEA. (e.g., see Example 4).

For ***claim 67***, Lagarde et al. does not disclose the use of a halogenated antibacterial agent in conjunction with said composition.

7. Claims 39, 62-64 and 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Lange (WO 88/00041) (Date of Patent is **14 January 1988**) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html).

For ***claims 39, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic dermatitis"; see also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** ... In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting

piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of an anion surfactant, Sodium Lauryl sulphate, in the same composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claim 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

For ***claim 67***, Lange does not disclose the use of a halogenated antibacterial agent in conjunction with said composition.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 39, 59-64 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lagarde et al. (WO 96/02226) (Date of patent is **February 1, 1996**) (translation provided) and FDA (Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis. 56 FR 63568, December 4, 1991, pages 1-3) as evidenced by Wikipedia (e.g., Wikipedia, "Category: Surfactants" last modified 24 November 2005, page 1, accessed on 12/3/05 at http://en.wikipedia.org/wiki/Category:Surfactants).

For ***claims 39, 61-64 and 67***, Lagarde et al. teach all the limitations stated in the 35 U.S.C. 102(b) rejection above (incorporated in its entirety herein by reference), which anticipates and, as a result, renders obvious claims 39, 61-64 and 67.

The prior art teaching of Lagarde et al. differ from the claimed invention as follows:

For ***claims 59 and 60***, Lagarde et al. differ from the claimed invention by not specifically reciting the use of a keratolytic agent.

However, FDA teach the following limitations that are deficient in Lagarde et al.:

For ***claims 59 and 60,*** FDA (see entire document) teaches the use of keratolytic agents like salicylic acid are suitable for topical application in the treatment of seborrheic dermatitis (e.g., see FDA, page 1, Sec. 358.701, page 2, Sec. 358.710, part (b)-(b)(4), "Active ingredients for the control of seborrheic dermatitis ... Salicylic acid, 1.8 to 3 percent").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use keratolytic agents like salicylic acid in the combination product as described by Lagarde et al. because the FDA explicitly approved this ingredient for its use in treating dandruff and seborrheic dermatitis, which is exactly what is being treated by said combination product. Furthermore, one of ordinary skill in the art would have been motivated to use "salicylic acid" as taught by the FDA with the combination product as taught by Lagarde et al. because the FDA states that active ingredients like salicylic acid are "recognized as safe and effective" for treating seborrheic acid. Furthermore, one of ordinary skill in the art would have reasonably

expected to be successful because the FDA approved the use keratolytic agents like salicylic acid for the treatment of dandruff and seborrheic dermatitis.

11. Claims 38-42, 48 and 53-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lange (WO 88/00041) (Date of Patent is **14 January 1988**) and FDA (Drug Products for the Control of Dandruff, Seborrheic Dermatitis, and Psoriasis. 56 FR 63568, December 4, 1991, pages 1-3) and Dascalu et al. (WO 96/29045) (Date of Patent is **September 26, 1996**) (of record) as evidenced by Green People (Green People, "Sodium Laurel Sulphate", **2002**, page 1, accessed on 12/3/05 at http://www.greenpeople.co.uk/Organics_Features_SLS.htm) and Avre Skin Care (Avre Skin Care, "Dermatology Dictionary", **2002**, pages 1 and 10, accessed on 12/3/05 at http://www.avro.co.za/misc/about_skincare/cosmetic_ingredients.html) and Dreumex (Dreumex, "Dreumex Liquid Soaps", no date, page 1, accessed on 12/3/05 at http://www.signus.com/dsoftsoap.htm) and Odds et al. (U.S. Patent No. 6,514,490) (Date of patent is **February 4, 2003**) and Brinkster (Brinkster, "The pH Scale", page 1, no date, accessed 12/3/05 at http://misterguch.brinkster.net/acidtutorial.html).

For ***claims 39, 41, 42, 56, 57, 62 and 63***, Lange (see entire document) discloses a two phase cleansing, conditioning and medicinal treatment shampoo and methods of use (e.g., see Lange, abstract), which anticipates the claimed invention. For example, Lange discloses a method for treating seborrheic dermatitis in a human patient in need thereof using said shampoo (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of them suffered from a grave seborrhoeic

dermatitis"; see also page 11, first full paragraph, "One may also use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "***The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant*** ... In a specific embodiment ***one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset)***, chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"). In addition, Lange discloses at least one 1-hydroxyl-2-pyridone of formula I as the active component (e.g., see Example 2, especially page 16, paragraph 2 wherein piroctone olamine is substituted for zinc pyrithion as the sole anti-mycotic; see also page 11, first full paragraph; see also page 13, first full paragraph, "One may also [i.e., in addition to phase I] use piroctone olamine in phase II because of its anti-seborrhoeic effect"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics [i.e., piroctone olamine is an anti-mycotic] in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine"; see also page 16, first full paragraph, "Similar or even better results were obtained when substituting piroctone olamine for zinc pyrithion [which refers to the "phase I" ingredients of Example 2 i.e., the phase II ingredient don't contain zinc pyrithion for such a substitution to occur]"; see also page 8, last paragraph). The active ingredient piroctone olamine, also known as 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone, falls within the scope of Applicants' formula (I) when R^4 = 2,4,4-trimethylpenyl (i.e., saturated hydrocarbon radical having 6 to 9 carbon atoms), R^1 = H, R^2 = methyl (i.e., alkyl having 1 to 4 carbon atoms) and R^3 = H. Furthermore, Lange discloses, for example, the use of

an anion surfactant, Sodium Lauryl sulphate, in the same composition (e.g., see top of page 15; see also page 16, paragraph 1 wherein piroctone olamine is "substituted" for the zinc pyrithion in that list of ingredients on the top of page 15). Lange does not state that sodium laurel sulphate is an anionic surfactant, but the Examiner contends that sodium laurel sulphate would inherently possess these properties as exemplified by Green People (e.g., see Green People, page 1, paragraph 1, "Sodium lauryl sulphate (SLS) is an anion surfactant ... which is included as a foaming agent ... in a huge variety of commonly used products ... shampoos").

For ***claims 48, 58, 64***, Lange discloses at least one "additional" surfactant such as lauramide DEA. Lange does explicitly state that "lauramide DEA" is a surfactant, but the Examiner contends that this would be an inherent property of the molecule as exemplified by Aver Skin Care (e.g., see Avre Skin Care, page 10 which discloses "lauramide DEA" as a nonionic surfactant).

For ***claim 67***, Lange does not disclose the use of a halogenated antibacterial agent in conjunction with said composition.

The prior art teaching of Lange differ from the claimed invention as follows:

For ***claims 38, 53, 65 and 66***, Lange fails to recite the use of a pH range between about 4.5 to about 6.5. Lange only teaches a "neutral" pH (e.g., see Lange, page 6, last paragraph). Although Lange does not define the term "neutral" in terms of a numeric range, the Examiner contends that a pH range between 6-8 is generally considered to be neutral for shampoo products (e.g., see Dreumex, page 1, "Dreumex has developed three types of liquid soaps: Each has a (neutral) pH-value of 6-7; see also Odds et al., column

5, last paragraph "Some of the first active ingredients when at approximately neutral pH (pH 6 to 8)"; see also Brinkster, "Solutions with a pH between 6 and 8 are usually referred to as 'neutral' by nonscientists"). Thus, Lange teaches a pH range that overlaps in scope with the present invention (i.e., pH 6-8 overlaps in scope with a pH of about 4.5 to about 6.5). In addition, Lange teach that lowering the pH to 4-5, using organic acids like lactic acid, do not adversely affect the anti-mycotic action of the 1-hydroxyl-2-pyridones like pirocton olamine (e.g., see page 10, paragraph 2) and provide favorable bacterio and mycostatic properties on their own (e.g., see Lange, page 15, bottom).

For ***claims 40, 55 and 61***, the combined references of Lange and FDA fail to teach the use of a cyclohexyl radical.

For ***claims 53, 54, 59 and 60***, Lange fails to recite the use of a keratolytic agent.

However, FDA teach the following limitations that are deficient in Lange:

For ***claims 38, 53, 65 and 66***, in the case where the claimed ranges "overlap or lie inside ranges disclosed by the prior art" a prima facie case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. cir. 1990). Here, the pH range disclosed by Lange (pH 6-8 for neutral solutions) overlaps with the claimed about 4.5 to about 6.5 range disclosed by applicant and, as a result, a prima facie case of obviousness has been set forth in accordance with *In re Wertheim* and *In re Woodruff*. Similarly, a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties (e.g., see *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227

USPQ 773 (Fed. Cir. 1985) (Court held as proper a rejection of a claim directed to an alloy of "having 0.8% nickel, 0.3% molybdenum, up to 0.1% iron, balance titanium" as obvious over a reference disclosing alloys of 0.75% nickel, 0.25% molybdenum, balance titanium and 0.94% nickel, 0.31% molybdenum, balance titanium.). Here, Lange teaches that a pH range of 4-6 can be used in the "phase II" solution (e.g., see page 10, paragraph 2), which indicates that pirocton olamine (which is used in both "phase I" and "phase II") would continue to function as anti-mycotic even at this lower pH range. Thus, a person of skill in the art would expect pirocton olamine to have the same anti-mycotic properties whether it was at a neutral pH (6-8) or a more acidic pH (4-5). In addition, a person of ordinary skill in the art would have been motivated to adjust the pH to 4-5 using lactic acid because of its favorable bacterio and mycostatic properties (e.g., see Lange, page 15, bottom of page).

For ***claims 40, 55 and 61***, Dascalu et al. (see entire document) teach the use of use of a cyclohexyl radical in the R^4 position (e.g., see claim 4; see also page 3, last paragraph).

For ***claims 53, 54, 59 and 60,*** FDA (see entire document) teaches the use of keratolytic agents like salicylic acid are suitable for topical application in the treatment of seborrheic dermatitis (e.g., see FDA, page 1, Sec. 358.701, page 2, Sec. 358.710, part (b)-(b)(4), "Active ingredients for the control of seborrheic dermatitis ... Salicylic acid, 1.8 to 3 percent").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to use keratolytic agents like salicylic acid in the medicinal

treatment shampoo because the FDA explicitly approved this ingredient for its use in treating dandruff and seborrheic dermatitis. Furthermore, one of ordinary skill in the art would have been motivated to use "salicylic acid" as taught by the FDA with the medicinal treatment shampoo as taught by Lange because the FDA states that active ingredients like salicylic acid are "recognized as safe and effective" for treating seborrheic acid. Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because the FDA approved the use keratolytic agents like salicylic acid for the treatment of dandruff and seborrheic dermatitis and also shows its use in conjunction with pyrithion zinc, which is explicitly disclosed as a preferred embodiment of Lange (e.g., see Lange, Example 2; see also abstract). In addition, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to made to use ciclopiroxolamine in the seborrheic dermatitis treatment described by the combined references of Lange and FDA because Dascalu et al. explicitly states that ciclopiroxolamine is useful for this purpose (e.g., see claims 1 and 4, "A composition for treatment of seborrheic dermatitis of the scalp ... consisting of ... ciclopiroxolamines"). Furthermore, one of ordinary skill in the art would have been motivated to use ciclopiroxolamines as taught by Dascalu et al. because Dascalu et al. teach that these compounds are a "preferred' embodiment (e.g., see claim 4) . Furthermore, one of ordinary skill in the art would have reasonably expected to be successful because Dascalu et al. teach several successful examples of using anti-fungal agents like ciclopiroxolamines (e.g., see claims and examples) and, in addition, it is

structurally related to the anti-fungal agents disclosed by the combined references of Lange and the FDA (e.g., 1-hydroxyl-2-pyridones are disclosed in each case).

Response

12. To the extent that Applicants' arguments as applied to previous Saint-Leger and Lange 35 U.S.C. § 103 rejection can be applied to the current 35 U.S.C. § 102 and § 103 rejections using the Lange reference, the following comments are noted.

[1] Applicants argue, "Lange does not teach or suggest employing 1-hydroxyl-2-pyridones for the treatment of anything more than symptoms of seborreheic dermatitis and quote a passage from the Board decision in support of their argument (e.g., see 3/15/05 Response, page 28, last paragraph).

[2] Applicants argue, "The increasing market share of Loprox Shampoo, which is prescribed for the treatment of seborrheic dermatitis, firmly demonstrates the non-obviousness of the claimed invention (e.g., see 3/15/05 Response, pages 29-30; see also 37 CFR 1.132 Declaration by Steve Bradford).

This is not found persuasive for the following reasons:

[1] The Examiner respectfully disagrees. First, the term seborreheic dermatitis as used by Applicants is vague and indefinite and, as a result Applicants' arguments are moot (e.g., see 35 U.S.C. 112, second paragraph rejection above). Second, Applicants' quoted passage by the board addresses the "phase II" composition, not the "phase I" composition that is currently being used to rejection Applicants' claims, which is clearly used to treat seborrheic dermatitis (e.g., see page 12, Example 1, "Shampoo for psoriasis-like seborrhoic dermatitis"; see also page 13, paragraph 1, "The test persons were persons suffering from tenacious dandruff, while one of

them suffered from a grave seborrhoeic dermatitis"; see also page 8, paragraphs 1 and 2, "The phase I composition may contain anti-mycotics in the medicinal as well as the anti-dandruff variant ... In a specific embodiment one may use a water soluble anti-mycotic such as piroctone olamine (Hoechset), chemical name 1-hydroxyl-4-methyl-6-(2,4,4-trimethylpentyl)-2-(1H)-pyridinone"

[2] The Declaration under 37 CFR 1.132 filed 2/22/05 is insufficient to overcome the 35 U.S.C. § 103(a) rejection of claims 39, 59-64 and 67 based upon Lagarde et al. or the 35 U.S.C. § 103(a) rejection of claims 38-42, 48 and 53-67 based upon Lange as set forth above because:

Applicants do not establish a nexus between the claimed features of the invention (e.g., pH range 4.5-6.5, use of cyclohexyl radical, use of keratolytic agent) and evidence of commercial success (e.g., see *In re Thompson*, 545 F.2d 1290, 192 USPQ 275 (CCPA 1976) ("Although commercial success is averred, there is no evidence showing that such success was attributable to the merits of appellants' invention rather than to other factors such as advertising.").

Applicants' arguments are not commensurate in scope with the claims (e.g., see *In re Grasselli*, 713 F.2d 731, 741, 218 USPQ 769, 777 (Fed. Cir. 1983) (Claims were directed to certain catalysts containing an alkali metal. Evidence presented to rebut an obviousness rejection compared catalysts containing sodium with the prior art. The court held this evidence insufficient to rebut the prima facie case because experiments limited to sodium were not commensurate in scope with the claims); see also *In re Tiffin and Erdman*, 171 USPQ 294 (CCPA 1971) and cases cited therein; see also MPEP § 716). In the present case, Applicants only provide evidence for one compound (e.g., Loprox), which is not commensurate scope with the large numbers of

currently claimed compounds of formula (I). Furthermore, there is no evidence that a compound of formula (I) is the "sole" active agent in Loprox (as required by independent claim 38) or has a pH range of about 4.5 to about 6.5 or that at least one "keratolytic agent" is being used (as required by independent claim 53).

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 38-42, 48 and 53-67 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-23 and 26-29 of copending Application No. 10/606,229. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both applications are drawn to the same treatment of seborrheic dermatitis using the same 1-hydroxyl-2-pyridone compounds having the same generic formula. Thus the applications overlap in scope.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D.
December 4, 2005

ANDREW WANG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

JASEMINE C. CHAMBERS
DIRECTOR
TECHNOLOGY CENTER 1600